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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application of

Lipson, David *et al.*

Application Number

09/711,440

Filing Date

November 13, 2000

For

**MEDICAL DIAGNOSTIC
METHODS, SYSTEMS, AND
RELATED EQUIPMENT**

Group Art Unit

3737

Examiner

Jung, William

Attorney Docket

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Appeal Brief Under 37 CFR §1.192

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This supports the appeal taken April 14, 2003 from the Final Rejection dated January 14, 2003.

1. Real Parties in Interest

The real parties in interest are the inventors, as there have been no assignments by either inventor of their rights in the invention.

2. Related Appeals and Interferences

There are no related appeals or interferences.

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3. Status of Claims

Claims 1-18 were filed. All claims are subject to final rejection and all are on appeal. No claims have been allowed or indicated as allowable if amended to overcome the rejection of a base claim.

Claims 1, 2, and 4 are independent.

4. Status of Amendments

No amendments have been presented after the Final Rejection. Claim 15 contains a minor problem in that it should read "at least *one* ocular opening" but this does not affect the scope of the claim.

5. Summary of the Invention

Referring to the preferred embodiments illustrated in the Figures only for convenience and not to limit the scope of the invention, it may be seen from Figure 1 that the invention involves diagnosis of stroke in a patient 4. Ultrasonic energy is generated in generator 5, then sent to and received from the patient 4 by transducer 6. The imager 9 interprets the reflected signal, which is affected (in part) by the nature and quality of the dynamic coupling 8 of the transducer 6 to the patient 4. "Dynamic coupling" as that term is used for purposes of the invention, is described at page 10, line 9 to page 12, line 3 of the specification. Actuator 7 improves the diagnosis of stroke in a closed feedback and control loop. Imager 9 performs any process for identifying data relevant to the diagnosis of stroke. An optional, non-ultrasonic, detection of symptoms of stroke, illustrated schematically as 10, may also be used confirm, modify, or reject a diagnosis of stroke; as an input to the dynamic coupling of transducer 6 to the patient 4; or as input to the imaging process.

Figure 2 is a schematic representation of another embodiment of the invention relevant to the claims on appeal. Transducer 6 is dynamically coupled to the patient 4 between transducer 6 and the patient's skull 11 in the vicinity of an opening 12. In the

embodiment shown in the Figure, an optional acoustic material **20** is used to improve the acoustic coupling of transducer **6** to the patient. Within the patient's brain **19** are several portions of cerebral vasculature that are imaged by the invention to diagnose stroke in the patient **4**. Artery **13** is blocked by blockage **14** and thus the flow of blood downstream is inadequate. Artery **15** is partially blocked by partial blockage **16**. Artery **17** is not blocked at all, but it has burst and thus diffuse blood flow **18** is present outside the vasculature and may be detected accordingly. Transducer **6** is used to diagnose any or all of these conditions in the patient in accordance with the principles of the invention.

6. Issues

Whether claim 1 is patentable under 35 USC § 102(b) over US 5,388,583 ("Ragauskas").

Whether claims 4-10, 13, and 18 are patentable under 35 USC § 103(a) over Ragauskas in view of US 3,948,248 ("Zuckerman").

Whether claims 2 and 3 are patentable under 35 USC § 103(a) over Ragauskas in view of US 6,019,724 ("Gronningsaeter").

Whether claims 11 and 14 are patentable under 35 USC § 103(a) over Ragauskas and Zuckerman, as applied to claim 4, and further in view of US 5,690,117 ("Gilbert").

Whether claim 12 is patentable under 35 USC § 103(a) over Ragauskas and Zuckerman, as applied to claim 4, and further in view of US 5,247,938 ("Silverstein").

Whether claim 15 is patentable under 35 USC § 103(a) over Ragauskas and Zuckerman, as applied to claim 4, and further in view of US 6,027,460 ("Shturman").

Whether claims 16-17 are patentable under 35 USC § 103(a) over Ragauskas and Zuckerman, as applied to claim 4, and further in view of US 6,027,460 ("Shturman").

7. Grouping of Claims

For purposes of this appeal, claim 1 stands alone; claims 2 and 3 stand together; claims 4-10, 13, and 18 stand together; claims 11 and 14 stand together; claim 12 stands

alone; claim 15 stands alone, and claims 16-17 stand together; but these seven groups of claims stand separately from each other.

8. Argument

- (i) Rejections under 35 USC § 112, first paragraph

Not applicable.

- (ii) Rejections under 35 USC § 112, second paragraph

Not applicable.

- (iii) Rejections under 35 USC § 102

Claim 1 was rejected as anticipated by Ragauskas.

Claim Construction

While it is true that the claims in a patent application are to be given their broadest reasonable interpretation consistent with a specification, *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), and that limitations from a pending application's specification will not be read into the claims during prosecution of a patent application, *Sjolund v. Musland*, 847 F.2d 1573, 1581-82, 6 USPQ2d 2020, 2027 (Fed. Cir. 1988), it is also well settled that an applicant may be his own lexicographer provided a specification sets forth supports the asserted definition, *Intellicall, Inc. v. Photometrics, Inc.*, 952 F.2d 1384, 1388, 21 USPQ2s 1383, 1386 (Fed. Cir. 1992).

“Dynamic coupling” as that term is used for purposes of the invention, is described at page 10, line 9 to page 12, line 3 of the specification in sufficient detail to appraise the person of ordinary skill that it is a defined term in this application.

Argument

A rejection under 35 USC § 102 requires that every element of a claimed invention be disclosed in a single reference. The reference must be read as the person of ordinary skill in the art would read it. The Examiner points to a selection of Ragauskas that, read as the ordinary artisan would read it, is a description of how a pair transducers 32, 34 may be aligned *prior to* use; or how such a pair may be *sequentially* deployed in such uses at multiple locations 38, 40, or 42; or how *multiple, independently but simultaneously operating* pairs of transducers could be so employed.

What the Examiner omits, and what he has not refuted except with a naked, unexplained denial (Final Action, page 2, paragraph 1), is that in none of these cases are any of the transducers *dynamically coupled* as that term is defined in the specification. This is clearly the intent of Ragauskas, as he prefaces his discussion of how transducers should be aligned according to the passage cited by the Examiner with, “[I]t is *essential* that the transducers 32, 34 are *held in a stable position once they have been aligned along a desired path such as 38, 40, or 42 ...*” (Column 5, lines 1-7) (*emphasis added*). Ragauskas teaches an adjustable—but *static*—frame system for accomplishing this: “a *rigid metal bar 50* adjustably attaches to band 44 and supports transducer 32, 34 at ends 52” (column 5, lines 15-16). The attachment mechanism is not described in text, but Figures 1, 21, and 22 of the reference, which is also a part of the disclosure that the ordinary artisan would consider, clearly depicts an arrangement that cannot reasonably be anything but a static, even if adjustable, apparatus.

Yet the specification clearly discloses that such a static system is *not* what dynamic coupling means: “dynamic coupling could be done by permitting *the transmitter/receiver to move ... [such as] back to its original location ...*” (specification page 10, lines 14-15, 21), or “dynamically controlling the amount an location ... of [a] vacuum, [such that] the transmitter/receiver is *dynamically* stabilized” (specification page 11, lines 6-7).

Because the disclosure of Ragauskas does not include dynamic coupling, as claim 1 properly interpreted in light of the specification requires, the rejection under 35 USC § 102 is improper and should be not be sustained.

(iv) Rejections under 35 USC § 103

Introduction

The claim construction advocated above also applies to applicant's position with respect to the rejections under 35 USC § 103.

Applicant has argued that the Examiner has not made out a prima facie case of obviousness as required under § 103. This argument was first set forth in detail in the Amendment filed October 7, 2002, and is repeated *verbatim* here (*emphasis added*):

Ragauskas does not actually teach or suggest a process or method including *dynamic coupling* of at least one ultrasonic transmitter/receiver to a skull, or to at least one opening in a skull, as each of the independent claims explicitly requires. In fact, Ragauskas teaches the exact opposite of one of the types of dynamic coupling taught at specification page 10, line 9 to page 12, line 3: "System 20 employs at least one pair of ultrasonic transducers 32, 34, which are mounted on a frame assembly 36 that can be mounted on a person's head. The frame assembly 36 can be formed in a variety of ways, however *it is essential that the transducers 32, 34 are held in a stable position once they have been aligned along a desired path* (Column 5, lines 1-7). Thus, a prima facie case for obviousness has not been made, as an element of every independent claim has not been shown to be in the prior art. Furthermore, there is no suggestion in the prior art (cited or otherwise) that the modification to the Ragauskas teaching that would be required to teach the claimed invention would lead to success, as required to support an obviousness rejection under 35 USC §103(a). In

fact, any such modification would be directly opposite to the explicit teaching of the reference, a strong indicator of non-obviousness.

This position is renewed in its entirety in this appeal. In response, the Examiner repeatedly argues only that “Ragauskas substantially discloses all of the claimed inventions” in the various claims as grouped above. All pending Final Rejections for obviousness rely on Ragauskas as the primary reference.

A Prima Facie Case of Obviousness Has Not Been Made

Every independent claim rejected for obviousness requires “dynamic coupling,” but Ragauskas does not teach dynamic coupling according to any interpretation of that term consistent with the specification. See the argument under section (iii), Rejections under 35 USC §102, supra.

Nor has the Examiner shown that any of the secondary references teaches dynamic coupling, or that the combination of the primary and secondary references together teaches dynamic coupling.

Claims 4-10, 13, and 18 are rejected over Ragauskas in view of Zuckerman. The Examiner cites Zuckerman for disclosure of diagnosis of stroke by blood flow analysis through the ocular system. The Examiner has not shown that Zuckerman makes up the deficiency in the primary reference by teaching dynamic coupling as that term is used in the claims consistent with the specification. In fact, the reference teaches a frame of the same adjustable static type as Ragauskas at column 8, line 63 to column 9, line 7 (referencing Figure 4), but the clear reading is that an apparatus in which the transducer is stationary during measurement is required.

Claims 2-3 are rejected over Ragauskas in view of Gronningsaeter. The Examiner cites Gronningsaeter for disclosure of the combination of ultrasound guidance combined with other imaging modalities. The Examiner has not shown that Gronningsaeter makes up the deficiency in the primary reference by teaching dynamic coupling as that term is used in the claims consistent with the specification. In fact, the reference teaches that the

ultrasonic transducer must be held in place relative to the cranium “to fix the ultrasound probe in the same position throughout the procedure” (column 7, line 46-48).

Claims 11 and 14 are rejected over Ragauskas in view of Zuckerman, as applied to claim 4, and further in view of Gilbert. The Examiner cites Gilbert for disclosure of diagnosis of partial blood flow blockage with a catheter inserted in the brain through a drilled hole. The Examiner has not shown that Gilbert makes up the deficiency in the primary reference by teaching dynamic coupling as that term is used in the claims consistent with the specification. In fact, the reference contains no apparent teaching of anything but manual insertion and removal prior to and after use, respectively.

Claim 12 is rejected over Ragauskas in view of Zuckerman, as applied to claim 4, and further in view of Silverstein. The Examiner cites Silverstein for disclosure of a catheter that “includes vacuum or suction to attach itself to a vessel or a tissue in the area of interest (col. 4, line 36-46; in reference to figures 2-4)” (Final Action, page 4, paragraph 8). The Examiner has not shown that Silverstein makes up the deficiency in the primary reference by teaching dynamic coupling as that term is used in the claims consistent with the specification. At best, all this reference teaches is the bare idea that a suction could be applied, but nothing to suggest “dynamically controlling the amount and location ... of the vacuum [such that] the transmitter/receiver is dynamically stabilized” as the ordinary artisan would understand the claims to include from page 11, lines 6-7 of the specification.

Claim 15-17 are rejected over Ragauskas in view of Zuckerman, as applied to claim 4, and further in view of Shturman. The Examiner cites Shturman for disclosure of an ultrasound catheter that “may be inserted in the patient via nose, ear and throat (col. 1, line 9-17)” (Final Action, page 5, paragraph 9). With respect to all three of claims 15-17, the Examiner has not shown that Shturman makes up the deficiency in the primary reference by teaching dynamic coupling as that term is used in the claims consistent with the specification. Shturman is another type of manually inserted/removed catheter with no apparent disclosure of a dynamic coupling system as the rejected claims require.

Therefore, the art of record, alone or in combination, does not include every claimed element, as required to support an obviousness rejection. This alone renders allowable the independent and dependent claims rejected for obviousness. MPEP §2143.03.

Deficiencies in Teachings

Regarding claim 12, the Examiner is correct that Silverstein teaches use of vacuum or suction “to attach [the catheter] *to a vessel or tissue in the area of interest*” (emphasis added), but please note that claim 12 specifically requires “applying a vacuum *to the skull*” (emphasis added). Silverstein’s catheter is invasive; it must be introduced through the skull into the soft tissue of the brain and vessels to perform its intended function. The person of ordinary skill in the art would not have been motivated to modify the Silverstein teaching of *vessel or tissue in the area of interest* to apply a vacuum *to the skull* given the extremely different degrees of hardness between the two types of target sites, and the well-known clinical difference between the two.

Regarding claim 15 alone, the Examiner asserts that Shturman’s disclosure applies to “any openings [in] the brain, which includes ocular openings” (Final Action, page 5, paragraph 9). There is no justification for this assertion. An electronic search of Shturman reveals neither “ocular” or “eye” or portions of the same. Also, immediately after the specific passage cited by the Examiner, the reference states, “Typically, the elongated medical device is introduced percutaneously, providing access to some remote location within the body, such as, *e.g.*, a coronary artery.” The person of ordinary skill in the medical diagnostic art, having a relatively high degree of training in anatomy, would not equate percutaneous access to the brain with ocular access. Given the specialized nature of the medical devices taught in the primary and secondary references, there is no basis for the Examiner’s assumption that Shturman’s catheters would successfully work outside their disclosed environment. Absent a showing of motivation to make the modification suggested by the Examiner, coupled with an expectation of success, a *prima facie* case of obviousness has not been made.

Teaching Away

As quoted above, Ragauskas, at best, teaches that one may select from multiple locations on the brain or cranium *prior to selecting a single location* at which a measurement is made: “[I]t is *essential* that the transducers 32, 34 are *held in a stable position once they have been aligned along a desired path ...*” (Column 5, lines 1-7). The invention, as claimed with the scope that is understood in light of the specification, proceeds in directly the opposite direction to the explicit teaching of Ragauskas, a strong indicator of non-obviousness.

The weakness in the Examiner’s position on this issue is especially evident when one considers that there is no disclosure in the Ragauskas system of any signal processing hardware or software that would accommodate a dynamically coupled system as claimed.

Conclusion

For the reasons given above, the pending rejections under 35 USC § 103 are improper and should be not be sustained.

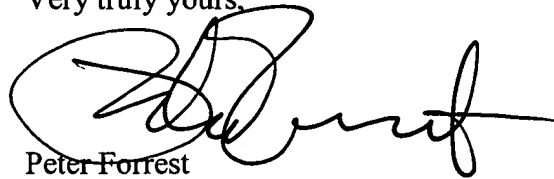
(v) Rejections under other provisions

Not applicable.

9. Appendix

The Appendix contains a copy of the claims on appeal.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Peter Forrest', written over a circular stamp or seal.

Peter Forrest
Registration No. 33,235

July 14, 2003

Appendix
CLAIMS ON APPEAL

1. Diagnosing stroke using dynamic coupling of at least one ultrasonic transducer/receiver to a skull.
2. Using non-ultrasonic detection of symptoms of stroke to dynamically couple an ultrasonic transducer/receiver to a skull.
3. The method of claim 2 in which the non-ultrasonic detection comprises at least one of the group consisting of computed tomography scanning, magnetic resonance scanning, differential spectrophotometric methods, near-infrared detection of tissue characteristics, detection of a biological material, measurement of a biological material, detection of a chemical, measurement of a chemical, detection of S100 β , measurement of S100 β , use of biological assay techniques, detection of change in blood pressure, detection of change in pressure within the eye, detection of change in blood flow in arteries serving organs other than the brain, or detection of change in blood flow in the arteries serving the eye.
4. For a patient having a skull containing brain tissue and blood vessels, a process for diagnosing stroke in the patient, comprising:
 - a) dynamically coupling at least one ultrasonic transmitter/receiver to at least one opening in the skull of the patient;
 - b) imaging a region within the skull of the patient; and
 - c) at least one of: determining presence of hemorrhagic stroke by identifying relatively diffuse blood flow within the skull of the patient; determining presence of ischemic stroke by identifying at least one location of inadequate blood flow within the skull of the patient; and diagnosing between hemorrhagic and ischemic stroke by classifying a region within the skull of the patient in terms of adequacy of blood flow.

5. The process of claim 4, in which the imaging comprises generating and receiving ultrasonic signals suitable for processing into information about the region within the skull of the patient.
6. The process of claim 4, in which a region is classified in terms of normal blood flow.
7. The process of claim 4, in which a region is classified in terms of inadequate blood flow.
8. The process of claim 4, in which a region is classified in terms of relatively diffuse blood flow.
9. The process of claim 4, in which locations of hemorrhagic stroke are determined by identifying relatively diffuse blood flow outside the blood vessels of the brain.
10. The process of claim 4 in which locations of ischemic stroke are determined by identifying relatively inadequate blood flow within the blood vessels of the brain.
11. The process of claim 4 in which presence of ischemic stroke is determined by identifying at least one location where there is at least partial blockage of blood flow.
12. The process of claim 4, further comprising applying a vacuum to the skull.
13. The process of claim 4, further comprising applying an acoustic coupling material to the skull.
14. The process of claim 4, in which the ultrasonic transducer/receiver is coupled to at least one man-made opening in the skull.
15. The process of claim 4, in which the ultrasonic transducer/receiver is coupled to at least ocular opening in the skull.
16. The process of claim 4, in which the ultrasonic transducer/receiver is coupled to at least one nasal opening in the skull.

17. The process of claim 4, in which the ultrasonic transducer/receiver is coupled to at least one aural opening in the skull.
18. The process of claim 4, in which the ultrasonic transducer/receiver is coupled to at least one acoustic bone window in the skull.

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